K012145

SECTION 11

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared;

a. Submitter's Name:

Robert Rosenbluth
President and CEO
MicroVention, Inc.
72 Argonaut
Aliso Viejo, CA 92656

b. Contact Person:

Jay Lenker, Ph.D.
Vice President, Scientific Affairs
MicroVention, Inc.
72 Argonaut
Aliso Viejo, CA 92656

c. Date Summary Prepared: July 2, 2001

2. Name of device, including trade name and classification name:

a. Trade/Proprietary Name: MicroVention MicroPlex Coil System (MCS)

b. Classification Name:

Device, Artificial Embolization
Regulation Number: 882.5950
Product Code HCG
Device Class: III

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Predicate Devices	Company	Description	Clearance Date
K002056	Micrus Corporation	Micrus Microcoil Delivery System	1/11/2001
K993417	Target Therapeutics	GDC-10 and GDC-18 Guglielmi Detachable Coil (3D Shape GDC)	1/21/2000
K991139	Target Therapeutics	Guglielmi Detachable Coil (GDC)	12/22/1999
K951256	Target Therapeutics	Detachable Platinum Coil (Guglielmi Detachable Coil)	9/8/1995

4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The MicroVention MicroPlex Coils are available in two versions: (1) Complex-shaped configurations, and (2) helically-shaped coil configurations of various diameters and dimensions. These embolization coils are fabricated from a platinum alloy wire, which is first wound into a primary coil, and then formed into the secondary complex or helical shape.

The MicroPlex Coils are provided attached to a Delivery Pusher. The MicroPlex Coil is detached from the Delivery Pusher by applying pressure force, with radiographic contrast media, at the proximal end of the Delivery Pusher. Once the embolization coil is detached, the Delivery Pusher is then removed from the microcatheter and discarded.

5. Statement of intended use:

The MicroVention MicroPlex Coil System (MCS) is intended for endovascular embolization of intracranial aneurysms that are considered by the treating neurosurgical team to be at very high risk for management by traditional operative techniques because of their morphology, their location or the patient's general medical condition, or are inoperable.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

The MicroVention MicroPlex Coil System (MCS) has the same technological characteristics as the predicate Micrus Corporation and BSC Target Therapeutics GDC coils. Both the materials of fabrication and the configuration of the coils are the same or very similar, with both the MicroVention and the predicate devices available in a variety of diameters and lengths to allow treatment of a variety of aneurysm sizes. Coil delivery is also similarly accomplished for the MicroVention MCS and for the predicate devices. The MicroVention MCS differs from the predicate devices with regard to the method used for coil detachment. Detachment of the MCS is effected by means of a detachment control syringe, which creates pressure at the proximal end of the Delivery Pusher. In contrast, the Micrus embolization coil is detached by heat-initiated shearing of a polyethylene fiber, and the Target Therapeutics GDC coils are released by means of electrolytic corrosion of a positioning wire near the junction of the coil.

7. Brief summary of nonclinical tests and results:

The non-clinical tests performed on the MicroVention MicroPlex Coil System (MCS) were based upon the intended use of the device, the performance of the predicate devices (GDC and Micrus) and an analysis of the failures of the predicate device (as based upon a review of applicable MDR reports). This testing included tensile strength, coil detachment, biocompatibility, and clinical simulation testing in animals.

This extensive body of testing has demonstrated that the MicroVention MicroPlex Coil System has performance substantially equivalent to that of the predicate devices, the Micrus Microcoil Delivery System and the Boston Scientific Target Therapeutics GDC system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2001

Mr. Vin Cutarelli
Vice President
Regulatory Affairs and Quality Assurance
MicroVention, Inc.
72 Argonaut
Aliso Viejo, California 92656

Re: K012145
Trade/Device Name: MicroVention MicroPlex Coil System (MCS)
Regulation Number: 882.5950
Regulation Name: Artificial Embolization Device
Regulatory Class: III
Product Code: HCG
Dated: September 4, 2001
Received: September 26, 2001

Dear Mr. Cutarelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K012145

Device Name: MicroPlex™ Coil System (MCS)

Indications for Use:

The MicroVention MicroPlex Coil System (MCS) is intended for endovascular embolization of those intracranial aneurysms that, because of their morphology, their location or the patient's general medical condition, are considered by the treating neurosurgical team to be very high risk for management by traditional operative techniques, or inoperable.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use ____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012145